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PATENT APPLICATION
Docket No. 7678.350.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
)
	Steven D. Jensen et al.)
)
Serial No.:	09/710,181) Art Unit
) 1616
Filed:	November 10, 2000)
)
Confirmation No.:	4245)
)
For:	COMPOSITIONS AND METHODS FOR)
	WHITENING AND DESENSITIZING TEETH)
)
Examiner:	Alton Nathaniel Pryor)
)
Customer No.:	022913)

REPLY BRIEF

Mail Stop: Appeal Brief–Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is being filed in response to the Examiner's Answer mailed December 20, 2011 pursuant to 37 CFR § 41.41. Appellants continue to appeal the rejection of claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94.

I. SUMMARY OF ARGUMENT

There were five rejections in the final Office Action dated July 18, 2011 (“Final Action”), an obviousness rejection under 35 U.S.C. § 103(a) and four obviousness-type double patenting (“ODP”) rejections. The same rejections were essentially repeated verbatim in the Examiner’s Answer. The Examiner’s Answer, like the Final Action, fails to make a *prima facie* case of obviousness and ODP. In addition, the Examiner’s Answer fails to address several important points raised in the Appeal Brief.

II. THE CLAIMS ARE PATENTABLE OVER FISCHER

As set forth in the Appeal Brief and previous responses to office actions, claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are patentable and unobvious over the art of record, including U.S. Patent No. 5,851,512 to Fischer et al. (“Fischer”), because each and every one of the claims defines (1) a desensitizing bleaching composition that (2) includes a dental bleaching agent in an amount so as to have a tooth bleaching effect and (3) a potassium nitrate desensitizing agent within one of three narrowly tailored concentration ranges that are neither taught nor suggested by the art of record, including Fischer (*i.e.*, about 0.01% to less than 2%, about 0.05% to about 1%, and about 0.5%).

The following claims each recite a dental bleaching composition or method of using the dental bleaching composition that includes potassium nitrate in a narrowly tailored range of about 0.01% to less than 2% by weight of the composition: 41-42, 44-45, 47-48, 50-54, 56-58, 72-76 and 86-87. In rejecting these claims, the Examiner’s Answer, like the Final Action, argues in relevant part that

Fischer teaches a dental composition comprising a desensitizing agent such as 0.1 – 10% potassium nitrate..., peroxides such as carbamide peroxide and hydrogen peroxide.... Example 8 used 10% urea peroxide.... Fischer differs from the instant invention in that

Fischer does not explicitly teach an invention to a non-abrasive composition of a dental composition that is substantially abrasive free. However, Fischer does not teach anywhere ... that his invention comprises an abrasive. Therefore, it is obvious that Fischer's invention is non-abrasive or substantially abrasive free.

Examiner's Answer, pp. 4-5.

A. The Examiner's Answer Fails to State a *Prima Facie* Case of Obviousness

The Examiner's Answer, like the Final Action, fails to state a *prima facie* case of obviousness of claims 41-42, 44-45, 47-48, 50-54. 56-58, 72-76 and 86-87 because it fails to show where Fischer teaches or suggests the combination of elements recited in the claims. For example, each of these claims requires

potassium nitrate in a range of about 0.01% to less than 2% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth.

The Examiner's Answer does not adequately address this claim element because it does not identify any teaching or suggestion in Fischer for including potassium nitrate in a dental bleaching composition within the narrowly tailored concentration range of "about 0.01% to less than 2% by weight" for treating sensitivity caused by a bleaching agent. Instead, the Examiner's Answer simply alleges that "Fischer teaches a dental composition comprising a desensitizing agent such as 0.1 – 10% potassium nitrate". Examiner's Answer, p. 4. Appellants note that the Fischer range is much broader than the narrow claimed range of "about 0.01% to less than 2% by weight". The narrowly tailored range excludes more than 80% of the values within Fischer's range (*i.e.*, from 2-10%). Notwithstanding this important difference, the Examiner's Answer, like the Final Rejection, fails to explain how Fischer discloses or suggests the narrowly tailored range of potassium nitrate. For this reason, the Examiner's Answer fails to state a *prima facie* case of obviousness relative to claims 41-42, 44-45, 47-48, 50-54. 56-58, 72-76 and 86-87.

Appellants are aware that a claimed range can be *prima facie* obvious over a prior art reference that discloses an overlapping range. MPEP 2144.05. However, it is still necessary under *Graham v. John Deere* for the PTO to properly ascertain the differences between the prior and claimed invention and the claims at issue to establish *prima facie* obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Examiner's Answer, like the Final Action, mentioned abrasiveness as *the only difference* between the claimed invention and Fischer (*see* Examiner's Answer, p. 5) but failed to identify and address other differences between claimed invention and Fischer, such as the *differences* between the concentration ranges of potassium nitrate recited in the claims (about 0.01-2%, 0.05-1% or 0.5%) and the range taught in Fischer (0.1-10%). *See* Examiner's Answer, pp. 4-5. The claimed amount of potassium nitrate is a critical difference, as has been argued in past responses to Office Actions and in the Appeal Brief.

Moreover, the claimed range is a narrow species overlapping a much broader genus in Fischer, which triggers application of special rules.

According to MPEP 2144.05,

Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing "(1) [t]hat the prior art taught away from the claimed invention...or (2) that there are new and unexpected results relative to the prior art." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004).

With regard to Fischer, the claimed invention satisfies both ways of rebutting *prima facie* obviousness, if it exists at all.

First, the Application is replete with teachings regarding the criticality of the claimed concentration ranges for potassium nitrate relative to maximizing its desensitizing effect when used in combination with a dental bleaching agent to treat bleaching induced sensitivity. As taught in the Application, while potassium nitrate was known to be an effective desensitizing agent at

concentrations of 3% and above when used by itself to treat *past* sensitivity, the inventors have surprisingly and unexpectedly determined that, when potassium nitrate is used *in combination with* a dental bleaching agent and applied to teeth for prolonged time periods, 3% or more potassium nitrate is *less effective* in treating *current sensitivity* caused by the dental bleaching agent than an amount of potassium nitrate within the narrowly tailored range of 0.01-2%. Application, p. 8, lines 11-22; p. 10, lines 10-13; p. 12, lines 7-11; p. 13, lines 5-10; p. 27, line 11 – p. 29, line 18. And unlike the present invention, Fischer does not distinguish between an amount of potassium nitrate that works best for preventing bleaching induced sensitivity rather than for treating pre-existing sensitivity.

The ability of potassium nitrate to provide higher than expected desensitizing activity at lower concentrations within the claimed narrow ranges “are new and unexpected results” which, according to *Iron Grip Barbell*, 392 F.3d at 1322, are sufficient to rebut *prima facie* obviousness of the claimed narrow ranges. It defies logic, common sense, and reason that including from about 0.01 to less than 2% potassium nitrate as in claims 41-42, 44-45, 47-48, 50-54, 56-58, 72-76 and 86-87 would actually provide *superior* desensitization than including 3% or more potassium nitrate. Yet that is precisely what was discovered by the inventors, as disclosed in the Application and confirmed by the Declaration of Dan E. Fischer, DDS Under 37 C.F.R. § 1.132 dated June 15, 2001 (“Fischer Declaration”).

Notwithstanding the clear teaching in the Application and Appellants’ previous responses that including potassium nitrate within the narrowly tailored ranges of about 0.01-2%, 0.05-1% or 0.5% is critical to the claimed invention, the Examiner’s Answer, like the Final Action, failed to address this important claim element, which clearly differs from the broad, non-specific range for potassium nitrate set forth in Fischer. Appellants also point out that Fischer is primarily directed to dental desensitizing compositions that generally do not include *any* dental bleaching agent, which is

merely an optional component. *See* col. 4, lines 41-43; col. 9, lines 36-42. It is noteworthy and instructive, and demonstrates differences between the claimed invention and the prior art, that Examples 1-7 and 9-10 include *no peroxide*, and urea peroxide *may* be added to Example 8 just prior to treatment (because of stability concerns). *See* col. 12, line 57 – col. 15, line 28. Fischer does not include any examples that show a composition that includes both potassium nitrate within the narrowly tailored range of about 0.01% to *less than* 2% by weight in combination with a dental bleaching agent.

Nor does Fischer distinguish between amounts of potassium nitrate that may be effective in treating *past* tooth sensitivity as compared to *present* sensitivity caused by the dental bleaching composition itself during tooth bleaching. In fact, Fischer specifically teaches that including 5% or more potassium nitrate provides a better desensitizing effect than including 0.5%, 1% or 2% (*see* col. 12, line 57 – col. 15, line 28), which teaches *away* from the claimed narrow ranges and therefore satisfies the other prong for rebutting *prima facie* obviousness set forth in *Iron Grip Barbell*, 392 F.3d at 1322.

Examples 1-8 of Fischer disclose desensitizing compositions that do not include any dental bleaching but which include anywhere from 0.5% potassium nitrate (Example 3) up to 10% potassium nitrate (Example 6), and several amounts in between, such as 1% (Example 4), 2% (Examples 1, 2 and 8), 5% (Example 7) and 7% (Example 5). *See* col. 12, line 57 – col. 15, line 28. Nowhere does Fischer teach or suggest the desirability of selecting a *lower* amount of potassium nitrate, especially not when used in combination with dental bleaching agents.

In fact, Fischer explicitly teaches that including 5% or more potassium nitrate provides the highest level of desensitizing activity. More particularly, Fischer teaches that compositions having the lowest quantities of potassium nitrate, as in Examples 3 (0.5%) and 4 (1%), provide “reduced but

significant desensitizing activity” (col. 13, lines 58-60; col. 14, lines 9-11). By comparison, Fischer teaches that compositions having the highest quantities of potassium nitrate, as in Examples 5 (7%) and 6 (10%), provide a “high level desensitizing activity” (col. 14, lines 25-26 and 41-42), while including 5% potassium nitrate as in Example 7 provides “a moderate to high level of desensitizing activity” (col. 14, lines 59-61). Thus, to the extent Fischer can be understood as disclosing a trend that would guide one of ordinary skill to select an amount of potassium nitrate to provide the highest level of desensitization, Fischer clearly advocates including *more* potassium nitrate to achieve the best desensitization. Thus, Fischer teaches away from the claimed narrow range, thereby rebutting *prima facie* obviousness according to *Iron Grip Barbell*, 392 F.3d at 1322.

In conclusion, Fischer fails to teach or suggest that including an amount of potassium nitrate within the claimed narrow range of about 0.01% to less than 2% will, when combined with a dental bleaching agent, provide the highest level of desensitizing activity as opposed to including substantially higher amounts (*e.g.*, 5%, 7% or 10% as in Examples 5-7 of Fischer). This is an unexpected result that rebuts *prima facie* obviousness. And to the extent Fischer can be understood as disclosing how to select an amount of potassium nitrate that maximizes desensitizing activity when used in combination with a dental bleaching agent, the amount is more than twice, and generally several times, the amount claimed (*i.e.*, 5%, 7% or 10% rather than 0.01-2%). This is a teaching away that further rebuts *prima facie* obviousness. Accordingly, Fischer fails to teach or suggest each and every element recited in claims 41-42, 44-45, 47-48, 50-54, 56-58, 72-76 and 86-87. Nor does the Examiner’s Answer or Final Action articulate any reason that would have prompted the skilled artisan to modify the teachings of Fischer in order to obtain a dental bleaching composition having an amount of potassium nitrate within the narrowly tailored range of about 0.01% to less than 2% by weight.

Claims 59-63, 77-80 and 91-93 claim an even more narrowly tailored concentration range of the instant invention for potassium nitrate centered around 0.5%, namely about 0.05-1%, and are therefore further distinguishable over Fischer. Appellants note that this range excludes more than about 90% of the values within Fischer's range (*i.e.*, from about 1-10%). Moreover, this range includes amounts of potassium nitrate that were identified in the Examples of Fischer as providing *the least amount* of desensitizing activity (*i.e.*, 0.5% and 1%) and therefore less desirable as compared to compositions that includes more potassium nitrate (*i.e.*, 2%, 5%, 7% and 10%). Finally, the upper range endpoint (about 1%) is about *half* the amount of potassium nitrate (2%) in the only example of Fischer (Example 8) that includes both potassium nitrate and dental bleaching agent.

Finally, claims 46, 61, 65-68, 70-71 and 81-85 claim the most narrowly tailored concentration range for potassium nitrate centered around 0.5%, namely "about 0.5%", and are therefore more distinguishable over Fischer than any other claims in the Application. Appellants note that this range excludes approximately 95% of all concentration values within Fischer's range of 0.1-10%. Moreover, this range explicitly claims the specific amount of potassium nitrate (0.5%) identified in Fischer as providing *the least amount* of desensitizing activity but which was found to provide the most desensitizing activity according to the Application and comparative study. Appellants also note that "about 0.5%" is only about *one fourth* the amount of potassium nitrate (2%) in the only example of Fischer (Example 8) that includes both potassium nitrate and dental bleaching agent.

B. Appellants' Comparative Test Data Showing Superior Desensitization When Using An Amount Of Potassium Nitrate Within The Claimed Ranges Instead Of Amounts Outside The Ranges Rebutts *Prima Facie* Obviousness

The Examiner's Answer states that "Appellants point to the Declaration of Dan Fischer filed 6/25/01 showing unexpected results for a dental composition comprising 10.5% carbamide peroxide

(bleaching agent) plus 0.5% potassium nitrate (desensitizing agent)” and summaries Appellants’ arguments that the comparative testing provides evidence of unexpected results. The Examiner’s Answer further states that “Examiner agrees with the Appellants” but argues that “Appellants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% and 10.5% carbamide peroxide.” This is clearly erroneous.

Appellants in fact tested *five different dental bleaching compositions*: a first composition (A) that included 0% potassium nitrate and 10% carbamide peroxide, a second composition (B) that included 3% potassium nitrate and 10% carbamide peroxide, a third composition (C) that included 3% potassium nitrate and 10% carbamide peroxide, a fourth composition (D) that included 3% potassium nitrate and 15% carbamide peroxide, and a fifth composition (E) that included 0.5% potassium nitrate and 10.5% carbamide peroxide. Fischer Declaration, ¶ 12; Application, pp. 27-29. Three data points for compositions that contained 3% potassium nitrate were compared to two other data points for compositions that contained 0% and 0.5% potassium nitrate, respectively.

The test data relating to these five data points are tabulated in paragraph 13 of the Fischer Declaration and pages 27-29 of the Application and reference six (6) different categories of oral sensitivity experienced by users of the five different compositions, namely (column 3) “number of days sensitive to hot or cold (% of total days); (column 4) “number of days gums sensitive (% of total days); (column 5) “number of days tongue sensitive (% of total days); (column 6) “number of days throat sensitive (% of total days); (column 7) “number of patients reporting sensitivity to anything; and (column 8) “number of patients reporting no sensitivity to anything”. Fischer Declaration, ¶ 13.

As explained in paragraphs 14-17 of the Fischer Declaration, the data showed an unexpected trend: the three compositions with 3% potassium nitrate (B)-(D) were *far less effective* in providing

a desensitizing effect than the composition containing 0.5% potassium nitrate (E). Even more surprisingly, the data tabulated in paragraph 13 suggests that the three compositions with 3% potassium nitrate (B)-(D) actually caused *more* oral sensitivity than the composition that included *no* (0%) potassium nitrate (A). Fischer Declaration, ¶ 13. This is contrary to what one of ordinary skill in the art would have expected and predicted in view of the clear teachings of Fischer that increasing the amount of potassium nitrate from 2% to 5%, 7% or 10% will provide a greater desensitizing effect in patient's already suffering from tooth sensitivity. Appellants therefore discovered that more is not always better, and including potassium nitrate in a concentration within the narrowly tailored ranges in the claims works better for preventing bleaching induced sensitivity. Unlike the present invention, Fischer does not in fact distinguish between an amount of potassium nitrate that works best for preventing bleaching induced sensitivity rather than for treating pre-existing sensitivity.

In summary, three different compositions that included 3% potassium nitrate were compared against two other compositions that included 0% and 0.5% potassium nitrate, respectively, contrary to what is asserted in the Examiner's Answer. Moreover, the five different compositions tested for six different categories of oral sensitivity demonstrated clear trends: (1) the three compositions that contained 3% potassium nitrate caused the most oral sensitivity, which is surprising, unexpected and unpredictable given the opposite teachings of Fischer, (2) the two compositions that contained less than 3% potassium nitrate (0% and 0.5%) caused less oral sensitivity than the three compositions that contained 3% potassium nitrate, also contrary to Fischer, and (3) the composition that included 0.5% potassium nitrate caused less oral sensitivity than the composition that contained 0% potassium nitrate, which would be expected.

Based on the trends shown by the various test data points provided by five dental bleaching compositions tested for six different types of oral sensitivities, Appellants constructed, based on their

high degree of knowledge and expertise in the field of dental bleaching compositions, narrowly tailored concentration ranges for potassium nitrate for use in dental bleaching compositions that include a dental bleaching agent and cause bleaching induced sensitivity. When constructing the ranges, Appellants recognized that the upper and lower range end points needed to include 0.5% potassium nitrate and exclude 0% and 3% potassium nitrate. The three narrowly tailored concentration ranges that Appellants constructed satisfied these criteria. Appellants also note that 2% is only $\frac{2}{3}$ of 3%, while 3% is actually 50% greater than 2% (*i.e.*, $2 + 2(0.5) = 3$). That means there is substantial separation between the upper range endpoint and the 3% potassium nitrate included in three of the tested compositions. On the other hand, 0.01% potassium nitrate is infinitely greater than 0%, which means there is substantial separation between the lower range endpoint and 0% potassium nitrate. This high amount of separation between the claimed ranges and the amount of potassium nitrate in the comparative compositions was inserted into the claimed invention when the Application was initially filed in order to provide a clear demarcation between the invention and the prior art.

According to applicable rules and case law, an applicant is not required to claim only the specific data points of a comparative study. Moreover, the Examiner's Answer cites to no rule or case law that would require this. To the contrary, MPEP § 716.02(d) states that "the nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof". *See In re Kollman*, 595 F.2d 48, 56 201 USPQ 193 (CCPA 1979); *In re Lindner*, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972); *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). The comparative test data described in the Application and Fischer Declaration

provide ample support for interpolating the narrowly tailored ranges from the test data and are sufficient to rebut *prima facie* obviousness over Fischer to the extent that it exists at all.

Moreover, the assertion in the Examiner's Answer that Appellants must test compositions that included potassium throughout the full concentration ranges is not supported by any authority. And in any event, Examples 3-10 of the Application provide prophetic examples which, according to Appellants' experience and expertise, were expected to provide higher desensitizing activity than bleaching compositions including either 3% or more potassium nitrate or no potassium nitrate. The prophetic examples cannot be ignored without the Examiner providing contrary evidence that the conclusions in Examples 3-10 are unreliable.

Finally, the assertion in the Examiner's Answer suggesting that Appellants must also test a wide range of different concentrations of dental bleaching agent is unsupported by any authority. Appellants' invention was directed toward identifying amounts of potassium nitrate that provide superior desensitizing activity, not how much bleaching agent is required to bleach teeth and cause sensitivity as an undesired byproduct of bleaching. As clearly taught in the Application, the variable that responsible for causing tooth sensitivity is prolonged contact of dental bleaching agent with teeth, not the concentration of bleaching agent *per se*, and that using less potassium nitrate is far better than using more potassium nitrate for desensitizing teeth in the case of prolonged contact between a bleaching agent and a person's teeth. *See* Application, p. 3, line 24 – p. 4, line 3; p. 8, lines 16-20; p. 13, lines 5-10. In view of this, the Application teaches that "up to 10% or more" potassium nitrate can be used when contact times are short. Accordingly, it is prolonged contact between bleaching agent and teeth, not concentration of bleaching agent *per se*, that matters most relative to tooth sensitivity. Notwithstanding the foregoing, the claims on appeal do in fact claim relatively narrow concentration ranges for the dental bleaching agent based on Appellants' expertise

and knowledge in the field. Such ranges are consistent with and closely reflect the concentrations of bleaching agent used in the comparative study and disclosed in the Examples.

III. THE CLAIMS ARE NOT OBVIOUS OVER THE CLAIMS OF FISCHER

A. The Examiner's Answer Fails to State a *Prima Facie* Case of Obviousness-Type Double Patenting Over Any Claims of Fischer

The Examiner's Answer, like the Final Action, alleges that claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are obvious over claims 1-12, 15 and 16 of Fischer. Examiner's Answer, p. 7. This rejection, like the obviousness rejection of the claims over Fischer, identifies the difference between the claims at issue and claims 1-12, 15 and 16 of Fischer as relating to the inclusion of abrasives. *Id.* Moreover, the Final Action states that "Fischer does not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate [but] does suggest such an invention". Final Action, p. 8. This implies that claims 1-12, 15 and 16 of Fischer disclose a dental bleaching composition containing a dental bleaching agent and potassium nitrate, just outside the claimed ranges. This is erroneous. Claims 1-12, 15 and 16 of Fischer do not disclose dental bleaching compositions of any kind and do not include a dental bleaching agent of any kind in any amount.

And while the Fischer *specification* discloses the optional use of a dental bleaching agent, obviousness-type double patenting only involves an analysis of what is taught or suggested by the *claims* of Fischer, not the disclosure of Fischer. Since the obviousness-type double patenting rejection is based solely on claims 1-12, 15 and 16 of Fischer, but because these claims do not teach or suggest a dental bleaching composition or the inclusion of a dental bleaching agent, Appellants submit that claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are not *prima facie* obvious over claims 1-12, 15 and 16 of Fischer for this reason alone.

And while claims 21-23 of Fischer do in fact recite a “bleaching agent”, they do not specify any amount, much less an amount of “bleaching agent” that is effective in bleaching teeth. Nor is this inherent in claims 21-23 because Fischer discloses the use of peroxide bleaching agents to either disinfect or bleach teeth, not solely to bleach teeth. Col. 9, lines 36-42. Perhaps more importantly, claims 21-23 depend from claims 1, 18 and 20, which do not specifically require the inclusion of potassium nitrate, much less potassium nitrate in any particular amount. Instead, claims 1, 18 and 20 simply recite “a desensitizing agent for reducing dental pain sensations”. The term “desensitizing agent” is a genus that includes several species other than potassium nitrate and certainly does not disclose or suggest the specific selection of potassium nitrate from among the several disclosed species of desensitizing agent, much less in an amount falling within the narrowly tailored ranges of about 0.01-2%, about 0.05-1% or about 0.5% as recited in the claims at issue. The vagueness of claims 1, 18 and 20 relative to the identity and amount of the desensitizing agent, coupled with the vagueness of claims 21-23 relative to the amount of the dental bleaching agent, further supports Appellants’ position that claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are not *prima facie* obvious over claims 21-23 of Fischer.

B. Appellants’ Comparative Test Data Showing Superior Desensitization When Using An Amount Of Potassium Nitrate Within The Claimed Ranges Instead Of Amounts Outside The Ranges Rebutts *Prima Facie* Obviousness

For substantially the same reasons given above relative to the comparative test data rebutting *prima facie* obviousness of the claims over Fischer, Appellants submit that the comparative test data likewise rebuts *prima facie* obviousness-type double patenting over any *claims* of Fischer, to the extent it exists at all. And to the extent one were tempted to read the Fischer claims in light of the Fischer specification, the specification teaches away from using less potassium nitrate rather than more in order to maximize its desensitizing effect. This further rebuts *prima facie* obviousness. *See*

Iron Grip Barbell, 392 F.3d at 1322.

IV. THE CLAIMS ARE NOT OBVIOUS OVER ANY CLAIMS IN THE JENSEN PATENTS

A. The Examiner's Answer Fails to State a *Prima Facie* Case of Obviousness-Type Double Patenting Over Any Claims of Jensen '576 and Erroneously Disregards Comparative Test Data Rebutting *Prima Facie* Obviousness

The Examiner's Answer, like the Final Action, alleges that claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are obvious over claims 1-7 and 10-20 of U.S. Patent No. 6,368,576 to Jensen et al. ("Jensen '576"). Examiner's Answer, p. 9. In making this rejection, the Examiner asserts that

Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a method of applying a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent to teeth with the aid of a tray. Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

Id.

The Examiner's Answer, like the Final Action, fails to identify the specific teachings in any *claims* of Jensen '576 that allegedly "suggests" dental bleaching compositions that include potassium nitrate in a range of about 0.01% to less than 2% by weight". The only claim in Jensen '576 that actually discloses an amount of potassium nitrate is claim 10, which merely teaches that "potassium nitrate is included in an amount of *up to about 10%* by weight of said dental bleaching composition". Col. 20, lines 39-41 (emphasis added).

In response, Appellants submit that the teaching in claim 10 that "potassium nitrate is included in an amount of up to about 10% by weight" does not suggest to one of ordinary skill in the art that the highest level of desensitization when treating bleaching induced sensitivity is obtained

when including only about 0.01-2% by weight potassium nitrate. Neither the specification nor the claims of Jensen '576 distinguishes between an amount of potassium nitrate that is optimal for treating bleaching induced sensitivity and an amount that is optimal for treating past tooth sensitivity, as in the claimed invention. Moreover, the claimed range of about 0.01-2% excludes about 80% of all concentration values in the range of "up to about 10%". And to the extent that the specification of Jensen '576 is even relevant to understanding what is suggested by the range of "up to about 10%", the specification essentially mirrors claim 10 and is equally vague.

Moreover, the comparative test data showing the surprising, unexpected and unpredictable results of dental bleaching compositions that include an amount of potassium nitrate within the claimed range of about 0.01-2% rebuts *prima facie* obviousness-type double patenting over the *claims* of Jensen '576, to the extent it exists at all. *See Iron Grip Barbell*, 392 F.3d at 1322.

The Examiner's Answer, like the Final Action, fails to address how or where the claims of Jensen '576 disclose or suggest the even more narrowly tailored range of about 0.05-1% for potassium nitrate. Instead, the Examiner's Answer merely asserts that "Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention." Examiner's Answer, p. 9. This statement fails to adequately address the more narrowly tailored range of about 0.05-1% potassium nitrate, which excludes about 90% of all concentration values in the range of "up to about 10%" as disclosed in the claims of Jensen '576.

Finally, the Examiner's Answer, like the Final Action, fails to address how or where the claims of Jensen '576 disclose or suggest the most narrowly tailored range of about 0.5% potassium nitrate. Instead, the Examiner's Answer merely asserts that "Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and

0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention.” Examiner’s Answer, p. 9. This statement fails to adequately address the most narrowly tailored range of about 0.5% potassium nitrate, which excludes approximately 95% of all concentration values in the range of “up to about 10%” as disclosed in the claims of Jensen ‘576.

B. The Examiner’s Answer Fails to State a *Prima Facie* Case of Obviousness-Type Double Patenting Over Any Claims of Jensen ‘625 and Erroneously Disregards Comparative Test Data Rebutting *Prima Facie* Obviousness

The Examiner’s Answer, like the Final Action, further alleges that claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are obvious over claims 1-8, 10, 11, 13-19 and 23-26 of U.S. Patent No. 6,309,625 to Jensen et al. (“Jensen ‘625”). Examiner’s Answer, p. 11. In making this rejection, the Examiner asserts that

Although the conflicting claims are not identical, they are not patentable distinct from each other because both instant application and patent discloses a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent. USPN ‘625 does not require an abrasive. Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

Id.

The Examiner’s Answer, like the Final Action, fails to identify the specific teachings in any *claims* of Jensen ‘625 that allegedly “suggests” dental bleaching compositions that include potassium nitrate “in a range of about 0.01% to less than 2% by weight”. The only claims in Jensen ‘625 that actually disclose an amount of potassium nitrate are claims 2 and 3, neither of which teaches or suggest potassium nitrate “in a range of about 0.01% to less than 2% by weight”. Claim 2 teaches that “potassium nitrate is included in an amount in a range from *about 0.1% to about 50%* by weight of the dental bleaching composition”. Col. 20, lines 5-7 (emphasis added). Moreover, neither the specification nor the claims of Jensen ‘625 distinguishes between an amount of potassium nitrate that

is optimal for treating bleaching induced sensitivity and an amount that is optimal for treating past tooth sensitivity, as in the claimed invention.

The teaching in claim 2 of Jensen ‘625 relative to potassium nitrate concentration is even further afield than claim 10 of Jensen ‘576 relative to the narrowly tailored concentration range of about 0.01-2% and further leads away from the claimed invention. For example, in addition to including concentration values greater than 2% and “up to about 10%” as in claim 10 of Jensen ‘576, claim 2 of Jensen ‘625 further suggests including a concentration of potassium nitrate between about 10-50%, which *more than quintuples* the suggested concentration values for potassium nitrate beyond those suggested by claim 10 of Jensen ‘576. In fact, the range of about 0.01-2% excludes about 96% of all concentrations of potassium nitrate suggested in claim 2 of Jensen ‘625, which highlights the intrinsic narrowness and patentability of the claimed invention over the *claims* of Jensen ‘625.

In further support of Appellants’ position that the Examiner’s Answer, like the Final Action, fails to state a *prima facie* case of obviousness of the claimed invention over the *claims* of Jensen ‘625, Appellants point to the fact that claim 3 discloses a concentration range that teaches away from the claimed invention. Claim 3 of Jensen ‘625 teaches that “potassium nitrate is included in an amount in a range from *about 3% to about 10%* by weight of the dental bleaching composition”. Col. 20, lines 9-11 (emphasis added). As discussed throughout the Application, the present invention requires an amount of potassium nitrate that, *at maximum*, is substantially less than 3% by weight. Claim 3 of Jensen ‘625, by contrast, explicitly teaches that the *minimum* amount of potassium nitrate is 3% and suggests that including up to about 10% potassium nitrate is beneficial. Claim 3 certainly does not suggest using less than about 3% potassium nitrate, much less “about 0.01% to less than 2% by weight” potassium nitrate. The fact that claim 3 teaches away from the claimed invention shows

a clear trend such that the *claims* of Jensen ‘625, when taken collectively to include claims 2 and 3, actually teach away from the claimed invention and rebut *prima facie* obviousness. *See Iron Grip Barbell*, 392 F.3d at 1322.

Moreover, the comparative test data showing the surprising, unexpected and unpredictable results of dental bleaching compositions that include an amount of potassium nitrate within the claimed range of about 0.01-2% rebuts *prima facie* obviousness-type double patenting over the *claims* of Jensen ‘625, to the extent it exists at all. *See id.*

The Examiner’s Answer, like the Final Action, fails to address how or where the claims of Jensen ‘625 disclose or suggest the even more narrowly tailored range of about 0.05-1% for potassium nitrate. Instead, the Examiner’s Answer merely asserts that “Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention.” Examiner’s Answer, p. 11. This statement fails to adequately address the more narrowly tailored range of about 0.05-1% potassium nitrate, which excludes about 98% of all concentration values in the range of “about 0.1% to about 50%” as recited in claim 2 and all concentrations in the range of “about 3% to about 10%” as recited in claim 3, which also teaches away from the claimed range of about 0.05% to about 1%.

Finally, the Examiner’s Answer, like the Final Action, fails to address how or where the claims of Jensen ‘625 disclose or suggest the most narrowly tailored range of about 0.5% potassium nitrate. Instead, the Examiner’s Answer merely asserts that “Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention.” Examiner’s Answer, p. 11. This statement fails to adequately address the most narrowly tailored range of about

0.5% potassium nitrate, which excludes about 99% or more of all concentration values in the range of “about 0.1% to about 50%” as recited in claim 2 and excludes all concentrations in the range of “about 3% to about 10%” as recited in claim 3, which teaches away from the claimed range of about 0.5%.

C. The Examiner’s Answer Fails to State a *Prima Facie* Case of Obviousness-Type Double Patenting Over Any Claims of Jensen ‘370 and Erroneously Disregards Comparative Test Data Rebutting *Prima Facie* Obviousness

The Examiner’s Answer, like the Final Action, also alleges that claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are obvious over claims 1-23 of U.S. Patent No. 6,306,370 to Jensen et al. (“Jensen ‘370”). Examiner’s Answer, pp. 12-13. In making this rejection, the Examiner asserts that

Although the conflicting claims are not identical, they are not patentable distinct from each other because both instant application and patent discloses a method of applying a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent to teeth with the aid of a tray. Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

Id.

The Examiner’s Answer, like the Final Action, fails to identify the specific teachings in any *claims* of Jensen ‘370 that allegedly “suggests” dental bleaching compositions that include potassium nitrate “in a range of about 0.01% to less than 2% by weight”. The only claims in Jensen ‘370 that actually disclose an amount of potassium nitrate are claims 1, 2, 14 and 16, none of which teach or suggest potassium nitrate “in a range of about 0.01% to less than 2% by weight”. Claim 1 teaches that “potassium nitrate [is] included in an amount of *at least about 0.1%* by weight of the composition”. Col. 19, lines 53-55 (emphasis added). Moreover, neither the specification nor the claims of Jensen ‘370 distinguishes between an amount of potassium nitrate that is optimal for

treating bleaching induced sensitivity and an amount that is optimal for treating past tooth sensitivity, as in the claimed invention.

The teaching in claim 1 of Jensen '370 relative to potassium nitrate concentration is even further afield than either claim 10 of Jensen '370 or claim 2 of Jensen '625 relative to the narrowly tailored concentration range of about 0.01-2% and further leads away from the claimed invention. For example, in addition to including concentration values greater than 2% and "up to about 10%" as in claim 10 of Jensen '576 or up to about 50% as in claim 2 of Jensen '625, claim 1 of Jensen '370 specifies *no upper limit* to the concentration of potassium nitrate. In fact, the range of about 0.01-2% excludes about 98% of all concentrations of potassium nitrate suggested by claim 1 of Jensen '370, which highlights the intrinsic narrowness and patentability of the claimed invention over the *claims* of Jensen '370.

Claims 2, 14 and 16 of Jensen '370 disclose ranges with upper concentration limits of about 7% and 10%, respectively, which are still several times greater than the *maximum* amounts of potassium nitrate permitted by the claimed invention. Seven percent (7%) is in fact three and one half (3-1/2) times greater than 2%, and 10% is five (5) times greater than 2%. The concentration ranges of claims 2, 14 and 16 of Jensen '370 therefore do not suggest a concentration range "of about 0.01% to less than 2% by weight".

Moreover, the comparative test data showing the surprising, unexpected and unpredictable results of dental bleaching compositions that include an amount of potassium nitrate within the claimed range of about 0.01-2% rebuts *prima facie* obviousness-type double patenting over the *claims* of Jensen '370, to the extent it exists at all. *See Iron Grip Barbell*, 392 F.3d at 1322.

The Examiner's Answer, like the Final Action, fails to address how or where the claims of Jensen '370 disclose or suggest the even more narrowly tailored range of about 0.05-1% for

potassium nitrate. Instead, the Examiner's Answer merely asserts that "Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention." Examiner's Answer, pp. 12-13. This statement fails to adequately address the more narrowly tailored range of about 0.05-1% potassium nitrate, which excludes about 99% of all concentration values disclosed in claim 1 of Jensen '370, *essentially all* concentrations in the range disclosed in claim 2 of Jensen '370, and about 90% of all concentration values in the range disclosed in claims 14 and 16 of Jensen '370.

The Examiner's Answer, like the Final Action, fails to address how or where the claims of Jensen '370 disclose or suggest the most narrowly tailored range of about 0.5% potassium nitrate. Instead, the Examiner's Answer merely asserts that "Jensen et al. differ from the instant invention is that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01 to 2% potassium nitrate. However, Jensen et al. do suggest such invention." Examiner's Answer, pp. 12-13. This statement fails to adequately address the most narrowly tailored range of about 0.5% potassium nitrate, which excludes about 99.5% or more of all concentration values disclosed in claim 1 of Jensen '370, *all* concentrations in the range disclosed in claim 2 of Jensen '370, and about 95% or more of all concentration values in the range disclosed in claims 14 and 16 of Jensen '370.

CONCLUSION

Appellants note that while not every contention, allegation and characterization of the Examiner set forth in the Final Action and Examiner's Answer, or raised at any other time during the prosecution of this case, was specifically addressed herein, the lack of remarks concerning any particular contention, allegation or characterization advanced by the Examiner is not intended, and should not be construed, to constitute an admission or concession by Appellants.

For at least the reasons discussed herein, Appellants respectfully submit that the Examiner's rejections of the claims are unsupported by the facts in the record and further that the Examiner's Answer takes erroneous legal positions as noted above. Accordingly, Appellant requests that the Board reverse all rejections of claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 and issue a Notice of Allowance.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Respectfully submitted,

Dated: February 21, 2012

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